

LETTERS TO THE EDITORS

Regarding "Limb asymmetry in titanium Greenfield filters: Clinically significant?"

To the Editors:

We read with great interest the article by Greenfield et al. (*J Vasc Surg* 1997;26:770-5), which seems to reassure physicians that clinically significant pulmonary emboli (PE) do not occur more frequently in asymmetric titanium filters than in symmetric filters. We performed a similar retrospective study of 162 patients with titanium Greenfield filters to seek relationships between recurrent PE and filter tilt, strut asymmetry, or caval size.¹ We documented eight cases (4.9%) of recurrent PE after filter insertion, two of which were fatal (1.2%). The rate of recurrent PE related to strut asymmetry was statistically significant, but no relationship existed between recurrent PE and filter tilt or vena cava diameter. A possible limitation of the current study and our own study is the frequency of incomplete patient follow-up. In the current study, only 65% of known survivors had adequate follow-up. Of the patients who have died since filter placement, how frequently was PE the primary or contributing cause of death, and how vigorously was the possible diagnosis of PE pursued? The paper did not mention how recurrent PEs were diagnosed.

Interestingly, our interpretation of Dr. Greenfield's results led us to the conclusion that strut asymmetry probably does increase the likelihood of clinically significant PE. By subtracting the 35 patients with asymmetric filters from the total group of 373 patients with adequate follow-up, 338 patients with presumably symmetric filters remain. Of this group with symmetric filters, 9 patients had recurrent PE, for a recurrent PE rate of 2.7%. By our calculations, the relative risk for recurrent PE in patients with asymmetric filters is 3.3 times higher than in patients with symmetric filters. Although this difference does not reach statistical significance, the strong trend seen in Dr. Greenfield's study suggests that statistical significance might be reached if the sample size were increased. We could not prove a statistically significant relationship between the degree of transverse coverage of the inferior vena cava by the filter in recurrent PE, however, we also believe that incomplete caval coverage probably is a risk factor for recurrent PE.² We are reassured by both the relatively low rates of recurrent PE (3.2%) and the apparent moderate increased risk with asymmetric titanium inferior vena cava filters. Improved symmetry of struts with the stainless-steel over-the-wire Greenfield filters compared with the titanium device from either femoral approach may partially correct the problem of asymmetric filter deployment.² The right jugular venous access appears to improve filter deployment compared with either femoral approach.² Given the trend towards increased risk of recurrent PE in the group of patients with asymmetric distribution of filter struts and given the negligible risk of

judicious transcatheter attempts to improve leg distribution, we continue to espouse the latter remedy rather than simply "wait and see."

We would be interested in Dr. Greenfield's comments regarding the following subjects: the work-up of patients who may have suffered recurrent PE with a filter in place, the importance of caval coverage, and the requirement of second filters in cases where caval coverage is considered suboptimal.

Thomas B. Kinney, MD

S. C. Rose, MD

University of California, San Diego
UCSD Medical Center—Hillcrest

REFERENCES

1. Kinney TB, Rose SC, Valji K, Oglevie SB, Roberts AC. The influence of strut asymmetry, filter tilt, and caval size on recurrent pulmonary emboli with the titanium Greenfield inferior vena cava filter [abstract]. *J Vasc Interv Radiol* 1997;8:195.
2. Kinney TB, Rose SC, Weingarten KE, Valji K, Oglevie SB, Roberts AC. IVC filter tilt and asymmetry: comparison of the over-the-wire stainless steel and titanium Greenfield IVC filters. *J Vasc Interv Radiol* 1997;8:1029-37.

24/41/90265

Reply

To the Editors:

We are pleased to see other investigators conducting outcome assessments of patients with vena caval filters. These data frequently are absent in the radiology literature. In response to the query, the difficulty in obtaining follow-up is a source of bias in all such reports, but we are diligent in documenting the cause of death. Chart and autopsy review are conducted for all patients who die in our institutions, and family members are contacted in all other cases. Any clinical event thought to be associated with pulmonary emboli (PE) by the primary physician is considered a recurrent PE, and we recognize that this leads to overdiagnosis.

Trends, like beauty, are in the eye of the beholder and are just as ephemeral. The purpose of setting predetermined alpha levels for comparison of groups is to overcome this subjective bias. We stand by our initial report. With appropriate statistical methods and 0.05 as the significance level, we failed to reject the null hypothesis of no difference. We feel that the use of the relative risk is misleading without its appropriate confidence intervals. The authors report a three-fold increase in risk of PE associated with asymmetric position. However, the 95% confidence limits of -1.09 and 11.01 suggest a sizable standard error.¹

Although sample size may impact our findings, we will avoid errors in 95% of cases by relying on objective prob-

abilistic testing. One factor that may explain the differences in our findings is the definition of asymmetry that we suggested in our own report.² There are no standard definitions, so it is difficult to determine what criteria were used. It is also not possible to know how many filters that initially reported as asymmetric were corrected by manipulation or natural forces over time. We believe caval coverage is important, but it cannot be adequately determined without computed tomography imaging. In many cases, the appearance of asymmetry on plain film is modified when the elliptical shape of the cava is considered. In these cases, coverage appears adequate when three legs of the filter are in each half of the ellipse.

In our practice, patients with recurrent PE undergo objective imaging studies to determine whether there is thrombus propagating beyond the filter. If so, a second filter is placed proximal to it. In addition, when the patient is being anticoagulated, PT and activated partial thromboplastin time should be monitored to ensure that they are in the therapeutic range. In patients with clot that propagates beyond the filter, a second filter may be indicated when the filter truly fails to span the cava by computed tomography or when the diameter of the cava is near the upper limit of 28 mm.

The current report is the third to be published by us since the release of the titanium filter in 1990.²⁻⁴ Our conclusions regarding the role of asymmetry and recurrent PE

have been identical in all three reports. As our numbers increase, we will continue to publish outcomes for patients to provide a more definitive answer to the problem of sample size. In the meantime, appropriate statistical testing remains the best defense against subjective beliefs.

Lazar J. Greenfield, MD

Mary C. Proctor, MS

University of Michigan Medical Center
Ann Arbor, Mich.

REFERENCES

1. Dunn G, Everitt B. Clinical biostatistics. New York: Halsted Press, 1955. p. 105.
2. Greenfield LJ, Proctor MC, Cho KJ, Wakefield TW. Limb asymmetry in titanium Greenfield filters: clinically significant? *J Vasc Surg* 1997;26:770-5.
3. Greenfield LJ, Cho KJ, Proctor M, Bonn J, Bookstein JJ, Castaneda-Zuniga WR, et al. Results of a multicenter study of the modified hook-titanium Greenfield filter. *J Vasc Surg* 1991;14:253-7.
4. Greenfield LJ, Proctor MC, Cho KJ, Cutler BS, Ferris EJ, McFarland D, et al. Extended evaluation of the titanium Greenfield vena caval filter. *J Vasc Surg* 1994;20:458-65.

24/41/90264